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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,880	12/12/2003	John P. Fruehauf	02-1270-A	1031
7590 12/27/2007 McDonnell Boehnen Hulbert & Berghoff 32nd Floor 300 S.Wacker Drive Chicago, IL 60606			EXAMINER YAO, LEI	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 12/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/734,880

Applicant(s)

FRUEHAUF, JOHN P.

Examiner

Lei Yao, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 22-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,21 and 40-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendments*

The Amendment filed on 10/18/2007 in response to the previous Non-Final Office Action (14/18/2007) is acknowledged and has been entered.

Claims 20 and 40 are amended. Claims 42-43 are added. Claims 1-43 are pending.

Claims 1-19 and 22-39 have been previously withdrawn for non-elected invention.

Claims 20, 21, and 40-43 are under consideration.

The following office action contains NEW GROUNDS of rejection based on the amendment and new consideration. Applicant's arguments with respect to claims 20-21 have been considered but are moot in view of the new ground(s) of rejection.

### **Rejections Withdrawn**

1. The rejection of claims 20 and 21 under 35 U.S.C. 112, second paragraph, as being indefinite because recitation of laboratory designation of identifying a particular molecule is withdrawn in view of the amendments to the claims. However, the amended claims are rejected under the same statute for different reasons (see below).
2. The rejection of claims 20 and 21 under 35 U.S.C. 112, second paragraph, as being indefinite because it is not clear for the relationship between the term outside and inside of the parentheses "( )" is withdrawn in view of the amendments to the claims.
3. The rejection of claim 20 under 35 U.S.C. 102(b) as being anticipated by Cheng et al., is withdrawn in view of the amendments to the claim by deleting the term "plasminogen activator" in the claim.
4. The rejection of claims 20-21 under 35 U.S.C. 102(b) as being anticipated by Daschner et al., is withdrawn in view of the amendments to the claims by deleting the term "HIP116" in the claims.

**Rejection/objection Maintained**

**Specification**

The objection of the specification because it contains an embedded hyperlink and/or other form of browser-executable code at page 27, line 10, is maintained because the amendment filed on 10/18/2007 still contain the same embedded hyperlink or browser-executable code, as originally appeared in the specification on page 27, line 10, as "http://rana.lbl.gov/Eisen Software.htm". Applicant is again required to check currently amended and original specification to delete the embedded hyperlink or the browser-executable code. See MPEP § 608.01.

**The following is a New Ground of rejection based on the amendments and new considerations**

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 21, and 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because it is not clear how the claimed invention can be achieved by method steps recited in the claims. For example, the purpose (preamble) of the claimed invention is a method of identifying taxane resistant tumor or tumor cells. However, the method steps are drawn to comparing the gene expression between the tumor cells and the non-tumor cells. Since no gene expression levels are determined or compared in the resistant tumor cells vs sensitive tumor and since the comparison are merely determined between the tumor vs non-tumor cells as recited in the claims, it is not clear how the purpose (preamble) can be achieved and how the resistant tumor can be identified by the method steps recited in the claims. Clarification is required.

For the art purpose in this rejection, the claims are interpreted as either a method step of comparison of gene expression between the resistant tumor vs non-resistant tumor cells or a method step of comparison of gene expression between the tumor cells vs non-tumor cells.

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***New Matter***

Claims 20, 21, and 40-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that the claims as newly amended claims reciting GenBank numbers in the independent claims 20, 40, 42, and 43 are not supported by the specification. Instant specification as filed, although provides a list of names of altered gene expression in the chemotherapeutic drug resistant cells compared to the sensitive cells, does not provide sufficient support for the relationship of the names of genes associated with the GenBank Accession Nos recited in the amended claims.

***Written Description***

Claims 20, 21, 40-43 are rejected under 35 U.S.C. 112, first paragraph, as containing matter that was not described in the originally filed specification.

Claims are drawn to accession Nos from public databases: GenBank Accession No. AF458589, GenBank Accession No. U79283, GenBank Accession No. BC063851, GenBank Accession No. AY194849, GenBank Accession No. D00099, GenBank Accession No. L34673, GenBank Accession No. AF060181, GenBank Accession No. AF237631.

Claims are drawn to sequences incorporated by reference to an accession no. from a public database, and for which no structural identity is provided by nucleotide or amino acid sequence in the specification at the time of filing. One skilled in the art cannot determine from the written disclosure of the specification alone whether the sequence as claimed is identical to the sequence contained in the database under the accession no. at the time the application was filed.

One skilled in the art could not determine based on the accession no. alone which entry for a sequence was being claimed, if the sequence entry was modified or revised after the time of application filing. Further, because multiple sequence entries could have been made after the filing date, then any post-filing date sequences would raise an issue of new matter. Thus one skilled in the art would conclude that Applicants were not in possession of any of the claimed sequences referred to by accession no. based on the written disclosure in the specification alone.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 20, 21, 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Mechetner et al., (Clinical Cancer Research, vol 4, page 389-398, 1998) as evidenced by Sharom F (J Bioenerg Biomembr, vol 27, page 15-22, abstract) and Gottesman et al., (Nature review, col 2, page 48-58, 2002). All references are cited in 892 mailed 5/17/2006.

Claims 20, 40, 43, and 44 are drawn to a method for identifying tumor or tumor cells comprising the tumor that are resistant to taxane chemotherapeutic drugs comprising steps of determining and comparing the expression of ATPase and identifying increased expression of the gene in the resistant tumor cells, wherein the tumor or tumor cells are breast cancer sample (claims 21 and 41).

Due to the indefiniteness of claims (see 112 2<sup>nd</sup> rejection above), here the Office interprets the claimed method of identifying the taxane resistant cell comprising the method step of comparing the gene expression between the resistant and sensitive breast cancer cells.

Mechetner et al., disclose a method for identifying of a tumor and cells resistant to Taxol, a taxane chemotherapeutic drug, by increased P-glycoprotein (Pgp) expression in human breast cancer cells. P-glycoprotein is ATP transporter protein having ATPase activity as evidenced by Sharom F (line 13-15) and Gottesman et al., (page 49, col 3, para 2, to page 50). Mechetner et al., disclose that Pgp expression in the samples is determined by flow cytometry or immunohistochemistry (p 391, col 1). Mechetner et al., also disclose the comparison and quantization of Pgp expression in the clinical specimen of breast carcinoma from the patients treated and untreated with Taxol (p 393, col 2, last para and table 2). Mechetner et al., disclose that higher levels of Pgp expression in the samples resistant to Taxol and that the degree of Pgp expression strongly correlated with the degree of drug resistance in the clinical specimen studies (fig 3, page 395 and page 394, col 1, para 3). Mechetner et al., further disclose the degree of overexpression of Pgp in breast cancer will significantly contribute to the levels of clinical resistance to Taxol (p 396, col 1, last para).

Due to the indefiniteness of reciting GenBank Accession No. as stated above, the method disclosed by Mechetner et al., meet the limitation of claimed invention reciting a method of identifying a tumor cell comprising the steps of determining and comparing the overexpression of ATPase in breast cancer or tumor cells.

2. Claims 20, 21, 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Junkun et al., (J Cell Biochem, vol 53, page 135-144, 1993, provided before ) or Jankun et al., (US Patent 5679350, 1997, cited in 892 mailed 5/17/2006)

Claims 20, 40, 43, and 44 are drawn to a method for identifying tumor or tumor cells comprising the tumor that are resistant to taxane chemotherapeutic drugs comprising steps of determining and comparing the expression of urokinase receptor and identifying increased expression of the gene in the resistant tumor cells, wherein the tumor or tumor cells are breast cancer sample (claims 21 and 41).

Due to the indefiniteness of claims (see 112 2<sup>nd</sup> rejection above), here the Office interprets the claimed method of identifying the taxane resistant cell comprising the method step of comparing the gene expression between the tumor and non-tumor cells. The recitation identifying a tumor that are resistant to taxane has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Junkun et al., (JCB) disclose a method of determining and comparing the levels of expressing Urokinase plasminogen activator receptor (uPAR), alternative name of urokinase receptor as evidenced by Mesh word search in NCBI (provided before), expression on tumor cell and non-tumor cells. Junkun et al., disclose that the method steps comprise comparing Urokinase receptor expressed on breast cancer tissue/cells to normal breast tissue using immunohistochemical staining (page 137, col 2 to page 138 and figure 2). Junkun et al., further disclose that malignant tumors express higher levels (intensive staining) of uPAR than the normal breast tissues (page 137, col 2).

Jankun et al., (Patent 5679350) disclose a method of determining the levels of urokinase plasminogen activator receptor (uPAR) expressed on breast cancer tissues to normal breast tissue by immunohistochemical staining. Jankun et al., disclose that uPAR is highly expressed on the breast tumor compared to normal breast tissues (col 11, line 65- col 13).

Due to the indefiniteness of reciting GenBank Accession No. as stated above, the method disclosed by Jankun et al., meet the limitation of claimed invention reciting a method of identifying a tumor cell comprising the steps of determining and comparing the increased expression of urokinase receptor in normal and cancer breast cells.



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**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,  
Examiner  
Art Unit 1642

LY



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER